

REMARKS

Claims 1, 10-13, 30, 33 and 36 presently appear in this case. No claims have been allowed. The official action of May 1, 2007, has now been carefully studied.

Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a DNA sequence coding for a protein encoded by SEQ ID NO:4, which protein is herein designated IREN. The invention also relates to vectors and host cells and pharmaceutical compositions comprising such DNA. The invention also relates to a composition comprising a recombinant animal virus vector encoding a protein capable of binding a cell surface receptor and also encoding the IREN protein.

Claims 1, 2, 5, 10-13, 30, 33 and 36 have been rejected under 35 U.S.C. 102(b), as anticipated by or in the alternative under 35 U.S.C. 103(a) as obvious over Wallach et al. (WO97/37016). The examiner states that the genus of DNA sequences disclosed by Wallach is a small genus of DNA as compared to the entire genus of all DNA encoding any protein. Thus, the examiner concludes that because Wallach teaches a small genus of DNA encoding a TRAF-binding protein, the claimed species, i.e., SEQ ID NO:4 is considered to be in possession of the public. Thus, the examiner states that

Wallach anticipates the instant claims. This rejection is respectfully traversed.

In order to simplify the issues, claim 1 has now been amended to only claim the sequence consisting of the nucleotide sequence of SEQ ID NO:4. Besides the wild-cards, the sequence of Fig. 3 of Wallach et al. (note that the PCT publication relied upon by the examiner does not have sequence id numbers associated with the sequences) cannot be anticipated by this claim as it includes 117 additional nucleotides at the N-terminus in addition to those of SEQ ID NO:4. Thus, even disregarding the wild-cards in the sequence (and these wild-cards cannot be disregarded for the reasons presented in previous amendments), the sequence of Fig. 3 of Wallach cannot anticipate claim 1.

The sequence consisting of SEQ ID NO:4 would not have been obvious to one of ordinary skill in the art reading Wallach because one of ordinary skill in the art reading Wallach would not expect that a full TRAF-binding protein is encoded by Fig. 3. Reference is made to page 55, lines 4-6 of Wallach, where it states:

Clones 9 and 15 are partial clones, which lack their most 5' end of the coding DNA sequences. The deduced amino acid sequences shown in Figs. 3b, 4b and 5b, are all started from the first nucleotide of the respective clone.

As can be seen from the description of Fig. 3, at page 17, lines 19-20, the nucleotide sequence of Fig. 3 is that of the 5' end of clone 9. Thus, as Fig. 3 shows the nucleotide sequence of clone 9 and the specification explicitly states that the most 5' end of the coding DNA sequence is missing from clone 9, it would not be obvious to one of ordinary skill in the art that the TRAF-binding protein actually begins at nucleotide 118 of the sequence illustrated in Fig. 3. Thus, the specific sequence consisting of the sequence of SEQ ID NO:4 is not anticipated by the longer of sequence of Wallach nor is it made obvious thereby. The four wild-cards even make the sequence of SEQ ID NO:4 less obvious.

Claim 5 has been deleted as being duplicative of amended claim 1, which eliminates paragraph (b). Paragraph (b) of claim 1 was deleted so as to avoid being duplicative of claim 36, which claims this degeneracy using different wording. Claim 36 is directed to a DNA molecule consisting of a sequence coding for a protein encoded by SEQ ID NO:4. Thus, it encompasses additional sequences that result from the degeneracy of the genetic code, but it still uses the "consisting of" language and is therefore not anticipated by Wallach for the same reasons as discussed above. Wallach is much longer than the sequence of claim 36 and the particular

claimed fragment of the sequence of Wallach would not have been obvious to one of ordinary skill in the art.

Claim 10 has now been rewritten as an independent claim, but otherwise its scope has not been changed. The "Dictionary of Biotechnology", Second Edition, James Coombs, MacMillan Press Ltd. (London) 1992, at page 356, defines "vector" as:

A replicon used for the transformation of cells in gene manipulation. Small plasmids, viruses and bacteriophage are suitable vectors, since they are replicons in their own right. Artificial vectors are constructed by cutting and joining DNA molecules from different sources using restriction enzymes and ligases

The term "replicon" is defined at pages 294-295 as follows:

A length of DNA that is replicated as a unit from a single initiation site. An origin of replication sequence in a DNA molecule is required for its replication. In bacteria and viruses, there is usually one replicon per genome, whereas each eukaryotic chromosome contains many replicons. In genetic engineering, fragments of DNA bearing the required genetic characteristics are attached to a suitable host type and specific replicon to form a vector or cloning vehicle.

Copies of these pages are submitted herewith. This definition of "vector" is consistent with the use of "vector" in the present specification, for example, at page 13, lines 19-22, which states:

In yet another aspect, the invention provides a vector comprising any of the

above DNA sequences according to the invention which are capable of being expressed in host cells selected from prokaryotic and eukaryotic cells; ...

Thus, claim 10 does not read on the sequence of Fig. 3 of Wallach. Wallach does not disclose putting the sequence of clone 9, or any part thereof, into a vector. It would not be obvious to put any part of the sequence of Fig. 3 of Wallach into a vector as Wallach teaches that this sequence is not a complete cDNA sequence, but that the 5'-most end of the cDNA is missing. As Wallach teaches that this sequence does not encode a complete TRAF-binding protein, there would be no reason for one of ordinary skill in the art to put that sequence into a vector. Accordingly, claim 10 is neither anticipated nor made obvious by Wallach. The same is true for the vector claims 11 and 12 and the cell claim 13.

Claim 33 is effectively a pharmaceutical composition comprising the DNA molecule of claim 36. Thus, claim 33 should be allowable for the same reason as discussed above with respect to claim 36.

Claim 30 is allowable in its own right as it requires a recombinant animal virus vector that encodes not only at least one IREN protein encoded by the cDNA sequence of SEQ ID NO:4, but also a protein capable of binding a cell surface receptor. It is not understood why the examiner considers this claim to be anticipated or obvious from

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Wallach. Wallach does not suggest any reason why the sequence of Fig. 3 thereof should be placed into a recombinant animal virus vector and certainly there is no disclosure of including in this vector a protein capable of binding a cell surface receptor. Accordingly, reconsideration and withdrawal of the rejection as to claim 30 is particularly urged.

As the present amendment to the claims obviates the only rejection of record in this case, reconsideration and withdrawal of this rejection are respectfully urged.

It is submitted that all the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By /rlb/
Roger L. Browdy
Registration No. 25,618

RLB:jmd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
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